

08/009,833


**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/009,833 01/27/93 ROBINSON

H UMMC91-03A

EXAMINER

SMITH, L

18N1/0725

ART UNIT

PAPER NUMBER

28

DATE MAILED: 1812

07/25/96

 PATRICIA GRANAHAN  
HAMILTON, BROOK, SMITH & REYNOLDS  
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LEXINGTON, MA 02173

 This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS
**OFFICE ACTION SUMMARY**
☒ Responsive to communication(s) filed on 6/17/96
☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

 A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, ~~whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).
**Disposition of Claims**
☒ Claim(s) 1, 2, 4, 7-14, 17-24 are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 2, 4, 7-14, 17-24 are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
**Application Papers**
☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.
**Priority under 35 U.S.C. § 119**
☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
**Attachment(s)**
☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

**BEST AVAILABLE COPY**

Serial Number: 08/009,833

-2-

Art Unit: 1813

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The examiner acknowledges the amendment filed and exhibits and the supplemental remarks and exhibits and declarations and amendments to the remaining claims. Claims cancelled are claims 3, 5, 6, 15 and 16 and claims pending and under consideration in this office action are claims 1, 2, 4, 7-14 and 17-24.

3. The rejection of claims 1, 2, 4, 7-14, 17-24 under 35 U.S.C. §112 second paragraph as failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicant's amendments to the claims.

4. The second rejection of claims 1, 2, 4, 7-14 and 17-24 under 35 U.S.C. §112 first paragraph as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure is withdrawn in view of applicant's amendment to delete the limitation of cell-mediated immunity from the claims.

5. The rejection of claims 1, 2, 4, 7-14, 17-24 under 35 U.S.C. §103 as being unpatentable over WO 90/11092 in view of Huylebroeck et al is withdrawn in view of applicant's remarks concerning the lack of predictability of success in obtaining

902-A

Art Unit: 1813

protection given the combination of teachings of the cited prior art.

Applicant's arguments filed 5/15/96 have been fully considered and are deemed to be persuasive only in part.

6. The objection to the specification and rejection of claims 1, 2, 4, 7-14, 17-24 under 35 U.S.C. §112 first paragraph is maintained essentially for reasons set forth in paper 22, paragraph 18 of the previous office action. It should be noted that this is a new grounds of rejection with respect to claims 21 and 24.

The objection to the specification and rejection of the claims was on the grounds that the specification lacked sufficient guidance and teaching to enable the broad scope of the claimed subject matter. The specification is enabling for claims limited to a method of immunizing a vertebrate against influenza virus infection comprising administering a DNA transcription unit comprising DNA encoding influenza virus hemagglutinin operatively linked to a promoter region whereby the vertebrate is protected from influenza disease.

Applicant urges that one of ordinary skill in the art given the teachings of the specification would be able to generate other DNA transcription units containing other influenza subtypes which would confer protective immunity or one of ordinary skill

40219

Art Unit: 1813

in the art would be able to generate DNA transcription units containing other antigens that would confer protective immunity.

It is the examiner's position that the claims are broadly drawn to a method of immunizing against an infectious agent comprising administering a DNA transcription unit encoding the protective antigen. In a previous response applicant had argued that one would not necessarily accept a correlation of immune responses generated in mice against, for example, HIV, with immune responses expected in humans. The claims encompass other antigens to which there is no teaching or guidance in the specification as to which antigens are considered to be important in generating protective immune responses. Moreover, applicant has submitted supplemental remarks urging that one would not have reasonably expected success with vaccinating with DNA, as instantly claimed, one of ordinary skill in the art would not have expected vaccination with DNA transcription units to be successful and that immunization with naked DNA is outrageous or dangerous. It would follow then, and adopting applicant's line of reasoning, that because of the unpredictability of success in vaccinating with DNA noted in the art, in view of the lack of guidance and teaching concerning antigens other than influenza H1 and H7 hemagglutinin and the ability of other antigens to generate protective immune responses when administered as a DNA transcription unit, one could not reasonably extrapolate to other

902C

Serial Number: 08/009,833

-5-

Art Unit: 1813

antigens from a showing of influenza hemagglutinin. Therefore, it is determined that the specification is not commensurate in scope with the claimed subject matter.

7. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Lynette F. Smith, Art Unit 1813 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1813 FAX telephone number is (703)-305-7939. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynette F. Smith whose telephone number is (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Should the examiner be unavailable, Supervisory Patent Examiner Christine M. Nucker may be reached at (703) 308-4028.

Smith/lfs *L78*  
July 23, 1996

*L. F. Smith*  
LYNETTE F. SMITH  
PRIMARY EXAMINER  
GROUP 1800  
*902-D*